

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Class 9/7141
9/10/91
 PATENT

In Re the Application of:

BARCLAY

Serial No.: 07/580,778

Filed: September 11, 1990

Atty. File No.: 2391-1

For: "PROCESS FOR THE HETER-
 OTROPHIC PRODUCTION OF
 MICROBIAL PRODUCTS WITH
 HIGH CONCENTRATIONS OF
 OMEGA-3 HIGHLY UNSAT-
 URATED FATTY ACIDS"

Group Art Unit: 188

Examiner: C. Geckle

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT PURSUANT
TO 37 C.F.R. §1.56

Honorable Commissioner of
 Patents and Trademarks
 Washington, D.C. 20231

<p>CERTIFICATE OF MAILING</p> <p>I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, DC 20231 ON THIS <u>20th</u> DAY OF <u>May</u>, 19<u>91</u>.</p> <p>SHERIDAN, ROSS & MCINTOSH</p> <p>BY: <u>Cheryl Schneider</u></p>

Dear Sir:

In order to meet the Applicant's duty of disclosure and duty of candor and good faith as required under 37 C.F.R. §1.56, the following information and references cited on the attached Form PTO-1449 are brought to the attention of the Patent and Trademark Office:

"Microorganism Production of Omega-3 Lipids" by Long, PCT International Application No. WO 89/00606 was cited as a prior art reference against Applicant during prosecution of the above-identified Application. Each of the references cited in this Supplemental Information Disclosure Statement and submitted herewith are related to the disclosure of Long and were published prior to Long's priority date of July 20, 1987. These references disclose the production of omega-3 highly unsaturated fatty acids by heterotrophically grown obligate or facultative marine eukaryotic microorganisms, specifically, Nitzschia, Cryptocodinium and Pythium. However, none of these references disclose the use of a microorganism of the order Thraustochytriales as a source of omega-3 highly unsaturated fatty acids for use in a food product.

Specifically, Tornabene et al. teach that the heterotrophic

microalga Nitzschia can produce omega-3 fatty acids. Strain LTP-1 and strain 3-2 of this species produces 10.8% to 21.8% and 16.6% to 29.1%, respectively, of their fatty acids as the omega-3 highly unsaturated fatty acid, eicosapentanoic acid. They also teach that the total lipid content of these strains, as percent dry weight, is 3.7% to 5.3% and 4.4% to 6.0%, respectively. Orcutt and Patterson teach that the average fatty acid content of five strains of Nitzschia, as percent of total lipids, is 54.9%. Therefore, one can calculate the approximate range of the omega-3 fatty acid content of these strains, as percent dry weight, to be 0.22% to 0.63% and 0.40% to 0.96%, respectively.

Harrington and Holz teach that the heterotrophic dinoflagellate Cryptocodinium produces omega-3 fatty acids. They report that this alga has 30% of its total fatty acids as docosahexanoic acid and that fatty acids were 5% of the dry weight of the alga. Thus, the omega-3 highly unsaturated fatty acid content of this alga can be directly calculated to be 1.5% of dry weight.

Haskins et al. teach that some Pythium species produce omega-3 fatty acids. They demonstrate that the Pythium strain PRL 2142 has 10.2% of its fatty acids as the omega-3 fatty acid, eicosapentanoic acid, and that Pythium strain PRL 26 has 9.1% of its fatty acids as eicosapentanoic acid. They also teach that the total oil content of the fungi is 70%, so it is easy to calculate the omega-3 content of the fungi on a dry weight basis. They report that the oil content of these fungi ranges from 1.6% to 11.7%, with the omega-3 fatty acid containing strains having a higher oil content. Thus, using 11.7% as the oil content of the omega-3 fatty acid containing strains and 70% of the oil as being fatty acids, the omega-3 fatty acid content of the above strains can be calculated to be 0.84% and 0.75% of cell dry weight, respectively.

The present invention teaches and claims the use of whole cell microorganisms of the order Thraustochytriales as a source of omega-3 highly unsaturated fatty acids in a food product, and the use of whole cell microorganisms of the order Thraustochytriales as a source of omega-3 highly unsaturated fatty acids or the extraction of omega-3 highly unsaturated fatty acids from these microorganisms wherein the microorganisms are cultured in a media with a low sodium concentration, or wherein these microorganisms have an omega-3 highly unsaturated fatty acid content greater than about 6.7% of total cell dry weight. In contrast, none of these prior art references disclose the use of whole cell microorganisms of the order Thraustochytriales as a source of omega-3 highly unsaturated fatty acids for use in a food product.

An Amendment and Response, a Declaration of William R. Barclay and a Request for Extension of Time accompany this Supplemental Information Disclosure Statement.

Respectfully submitted,

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Date: 5/20/91